

REMARKS

Claims 1-24 are pending in the application with claims 1, 12, 15, and 21 being the independent claims.

Rejection under 35 U.S.C. § 102

The Office Action indicated that claims 1-8 and 12-24 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,702,453 to Rabbe et al. (“Rabbe”).

Claims 1, 12, and 15

Claim 1 is directed to a vertebral implant. In particular, claim 1 recites:

*A vertebral implant for interposition between two vertebral endplates comprising:
a tubular body sized to fit between the two vertebral endplates;
a pair of ring-shaped cleat assemblies, each cleat assembly comprising an outer end wall, an inner end wall, and a side wall which defines a hollow bore, wherein one or more spikes extend from each outer end wall, and wherein each hollow bore is sized to fit over an end of the tubular body and slidably pass from the end along at least a portion of the length of the tubular body.*

Claim 1 is not anticipated because Rabbe does not disclose all of the features recited in claim 1. For example, Rabbe does not disclose a vertebral implant, with all the features of claim 1, including a pair of ring-shaped cleat assemblies with a hollow bore, “wherein each hollow bore is sized to . . . slidably pass from the end along at least a portion of the length of the tubular body.” Instead of being configured to “slidably pass” along a portion of the length of the body, Rabbe discloses a vertebral body replacement having a threaded cylindrical body (21) and threaded endplates (22) (column 5, lines 52-54), that are configured to engage each other (column 6, lines 7-12; column 7, lines 41-43).

However, a system that threadably advances endplates (22) over a threaded cylindrical body (21) does not anticipate a vertebral implant with cleat assemblies that “slidably pass” along a portion of the tubular body because threading and slidably passing are not the same thing. As

can be inferred by the disclosure, “slidably passing” is meant to mean axial movement without heavy threaded retention. See Specification, para. 16, 19 and 26. It should be noted that to “slidably pass,” components need not have smooth walls or be suitable for impacting, but instead must allow axial movement without heavy retention by threads.

Because Rabbe does not disclose a vertebral implant with all the features of claim 1, including a pair of ring-shaped cleat assemblies with a hollow bore, “wherein each hollow bore is sized to . . . slidably pass from the end along at least a portion of the length of the tubular body,” claim 1 should be allowable over Rabbe. Applicant respectfully requests that the Examiner withdraw the rejection and allow claim 1.

Independent claims 12 and 15 recite, respectively, a bore that may “slidably pass” and a bore for “slidably passing.” Accordingly, these claims should be allowable for at least the reasons discussed above. Applicant respectfully requests that the Examiner withdraw the rejection and allow claim 1.

Claim 21

Claim 21 is directed to a method for inserting a vertebral implant between two vertebral endplates. In particular, claim 21 recites:

A method for inserting a vertebral implant between two vertebral endplates, wherein the vertebral implant comprises a pair of cleat assemblies and a tubular body, the method comprising:
sliding the cleat assemblies over the tubular body;
inserting the vertebral implant between the vertebral endplates;
interposing a distracting device between the cleat assemblies;
applying a distracting force with the distracting device whereby at least one of the cleat assemblies is moved into engagement with at least one of the vertebral endplates.

Rabbe does not disclose all of the steps recited in the method of claim 21, and therefore, does not anticipate the claim. The Office Action states that the claimed method is inherently performed when installing the device disclosed in Rabbe. However, the process of installation

disclosed in Rabbe includes steps other than those of the claimed method and, therefore, the claimed steps cannot be inherent and claim 21 cannot be anticipated.

The installation process in Rabbe is described from column 7, line 31 to column 8, line 42. This process includes distracting the intact vertebrae with distraction forceps (column 7, lines 35-37). The threaded cylindrical body (21) is then threaded with the threaded endplates (22) to achieve the desired height (column 7, lines 38-43). Set screws (24) secure the endplates (22) in place on the body (21) (column 8, lines 13-18). The whole assembly is then disposed between the distracted vertebrae and the distraction forceps are removed (column 8, lines 36-42).

Rabbe's disclosed process fails to include the claimed method step of "sliding the cleat assemblies over the tubular body," using the definition discussed above with respect to claim 1. Rabbe also fails to disclose the claimed method step of "interposing a distracting device between the cleat assemblies." In fact, Rabbe's distracting device does not operate on the implantable device at all. Finally, Rabbe fails to disclose the claimed method step of "applying a distracting force . . . whereby at least one of the cleat assemblies is moved into engagement with at least one of the vertebral endplates." Instead, in Rabbe, the distracting device operates only with the intact vertebrae and does not act on the implantable device. Because Rabbe does not disclose all the steps of the method recited in claim 21, this claim should be allowable. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection and allow claim 21.

Claims 2-8, 13, 14, 16-20, and 22-24 depend from and add additional features to independent claims 1, 12, 15, and 21. Therefore, these claims should be allowable for at least the reasons that their respective independent claim is allowable. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection and allow these claims.

Rejection Under 35 U.S.C. §103

The Office Action indicated that claims 9-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rabbe. However, claims 9-11 depend from and add additional features to independent claim 1. For the reasons discussed above, claim 1 should be in

condition for allowance. Therefore, claims 9-11 also should be allowable for at least those same reasons. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection and allow these claims.

Conclusion

For at least the reasons set forth above, independent claims 1, 12, 15, and 21 should be in condition for allowance. Dependent claims 2-11, 13, 14, 16-20, and 22-24 depend from and add additional features to the independent claims and, therefore, also should be in condition for allowance. Accordingly, Applicant respectfully requests that the Examiner withdraw the outstanding rejections and issue a formal notice of allowance.

Please grant any extension of time required to enter this response and charge any additional required fees to our Deposit Account No. 08-1394.

Respectfully submitted,



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| <p>I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450</p> <p>on: <u>November 4, 2005</u></p> <p><u>Kristina Pariza</u></p> <p>Signature of person mailing paper and fee</p> |
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